RDT Abbreviated 510(k) Submission – Tempus Pro (EF)

MAY 16 2014

5. 510(k) Summary of Safety and Effectiveness

5.1 Submitter's Information

The submitter of this abbreviated pre-market notification is:

Name:	Remote Diagnostic Technologies Limited
Address:	The Old Coach House, Farleigh Wallop, Basingstoke, RG25 2HT, United Kingdom
Company Phone No:	+44 (0) 1256 362 400
Company Fax No:	+44 (0) 1256 362 415
Contact Person:	Dr Leigh Cornock (Director of Systems Eng. & Test)
Date summary prepared:	10th April, 2014

5.2 Device Identification

Device Trade Name:	Tempus Pro
Common Name:	Patient Monitor (without arrhythmia detection or alarms)
Class:	II
Classification Panel:	74
Primary Product Code:	MWI
Primary Regulation Number:	870.2300

Secondary FDA product code	Regulation Number
Cardiac Monitor (DRT)	870.2300
Electrocardiograph (DPS)	870.2340
Impedance Plethysmograph (DSB)	870.2770
Non Invasive Blood Pressure Measurement System (DXN)	870.2770
Carbon Dioxide Gas Analyzer (CCK)	868.1400
Breathing frequency monitor (MNR)	868.2375
Oximeter (DQA)	870.2700
Clinical electronic thermometer (FLL)	880.2910
Computer, Blood-pressure (DSK)	870.1110
Transmitters and Receivers, Physiological Signal, Radiofrequency (DRG)	870.2910

5.3 Device Description

The Tempus Pro is a multi-parameter vital signs monitor designed for use in pre-hospital care and remote clinical locations by trained healthcare professionals. It provides 3&5 lead ECG monitoring, 12 lead ECG recording, pulse oximetry, non-invasive blood pressure, sidestream capnometry, contact temperature, impedance respiration, invasive pressure and user configurable alarms.

In addition, it provides the ability to transmit all vital signs data via wired or wireless connections to a software system (called i2i) expected to be based in a facility far from the user e.g. a response centre facility. In addition to sending all vital signs, the system can also send pictures or video via an integrated camera, geographic position by an integrated GPS receiver and voice via a wired or wireless headset.

5.4 Indications for Use

The following indications for use for the Tempus Pro remain unchanged by addition of the extended features for ECG recording, pulse oximetry and invasive blood pressure monitoring to the Tempus Pro, with the exception of removal of "(SpO2)" as additional pulse oximetry measurements are being added.

"The Tempus Pro is a portable vital signs monitor intended to be used by clinicians and medically qualified personnel for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications. The device is indicated for 3 & 5 Lead ECG monitoring and 12 Lead ECG recording with interpretation, impedance pneumography, non-invasive blood pressure (NIBP), end-tidal CO2 (ETCO2), respiration rate, pulse oximetry (SpO2), contact temperature, invasive pressure and extended pulse oximetry capability including; carboxy haemoglobin (SpCO), metheglobin (SpMet), total haemoglobin (SpHb) and total oxygen content (SpOC) measurements.

The monitor is intended to be used as a stand-alone monitor or as a telemedicine system (transmitting patient data to other medical professionals located elsewhere).

The device is indicated for adults, pediatrics and neonates."

5.5 Comparison with Cleared Device

The intended use and indications for use, plus the fundamental technology used in the Tempus Pro device, remain essentially unchanged by the addition of optional extended features to the ECG recording, pulse oximetry, and invasive blood pressure functions, which are specifically:

- Extended Pulse Oximetry capability to include optional carboxy haemoglobin (SpCO), metheglobin (SpMet) total haemoglobin (SpHb) and total oxygen content (SpOC) measurements
- Optional 12-Lead ECG Recording Interpretation
- 2 optional additional Invasive Blood Pressure Channels

5.6 Substantial Equivalence

In adding some of the optional features, it has been necessary to cite other predicates for specific functionality provided:

- Pulse Oximetry – new Masimo SET Rainbow module and associated sensors/patient cable, incorporating original SET oxygen saturation technology as used in cleared Tempus Pro plus 4 new measurement capabilities, is substantially equivalent to the same module incorporated into the Masimo Radical-7 device (K110028)
- Invasive Blood Pressure – additional external IBP module which uses same Medlab IBP module as already incorporated internally into the cleared Tempus Pro device (K130773)
- ECG Recording Interpretation – enabling the interpretation output of the mymisys32.dll, which is already an integral part of the cleared Tempus Pro, but the interpretation output is not currently displayed to the user. The dll is part of the CardioView software package from QRS Diagnostic (K083749).

Hence, the new pulse oximetry module with sensors and cables, the additional invasive blood pressure, and the ECG recording 12 lead interpretation are the same as those used by the original equipment manufacturers in their cleared devices.

The 510(k) numbers for the predicate devices to which we are claiming substantial equivalence are K110028, K130773, and K083749.

5.7 Summary of Non-Clinical Testing

All of the above modifications have been made under well-established design control procedures, which ensure that appropriate risk management processes have been carried out to determine their impact and ensure that appropriate verification/ validation testing is performed.

The non-clinical testing carried out in relation to addition of the extended features described above is summarized in the following table:

Area	Testing Performed
Safety	The device has been tested to IEC60601-1.
Defibrillation and electrosurgical protection	The device has been tested for operation with a defibrillator and operation with an electro-surgical unit according to IEC60601-1 (and relevant particular standards).
Environmental	The device has been tested to a range of environmental (temperature, altitude, humidity, vibration, shock) tests according to RTCA DO-160, MIL810, EN1789, EN13718-1, EN60068.
Ingress Protection	The device has been tested to IEC 60529 for solid and water ingress.
EMC	The device has been tested to IEC 60601-1-2 for emissions and immunity and RTCA DO-160 for radiated emissions. (including immunity at 20 V/m)
Invasive pressure	The device has been tested to IEC 60601-2-34.
Pulse oximeter	The device has been tested to IEC 9919.
Comparative testing to predicates	Comparative testing has been performed to demonstrate that the performance of the device is equivalent to the predicates.
Software	The requirements of the FDA document *Guidance for the Content of Premarket Submissions for Software in Pre-Market Submissions* has been applied. In addition, the requirements of IEC 62304 have been addressed.
Bench testing	All parameters of the device have been tested to confirm they operate to specification across their stated performance range and across their stated temperature range.
Bench testing	The product has been bench tested to confirm that all data is transmitted reliably and accurately.

Area	Testing Performed
Wireless co-existence testing	The thermometer has been tested to confirm it operates reliably in the presence of other wireless fields as per the FDA Guidance for Radio-Frequency Wireless Technology in Medical Devices.

In each case the results of this testing confirmed that acceptance criteria defined by the relevant standard, or other appropriate reference document had been met.

With respect to usability, no additional user validation was considered necessary, as the Tempus Pro (EF) is almost identical to the predicate Tempus Pro in terms of physical and interface features, including size and weight, user interface data layouts, button styles, menus, and layout of connectors, resulting the physical interaction with the device being unchanged.

5.8 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this Premarket Notification, Remote Diagnostic Technologies Limited conclude that this extended version of the Tempus Pro Patient Monitor is safe and effective, and substantially equivalent to the unmodified version of this device and other cleared devices used as predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 16, 2014

Remote Diagnostic Technologies Ltd.
Dr. Leigh Cornock
Director of Systems Engineering and Test
The Old Coach House,
The Avenue Farleigh Wallop,
Basingstoke, Hampshire, UK

Re: K133988
Trade/Device Name: Tempus pro extended features
Regulation Number: 21 CFR 870.2300
Regulation Name: Monitor, Physiological, Patient (Without Arrhythmia Detection or Alarms)
Regulatory Class: Class II
Product Codes: MWI, DRT, DPS, DSB, DXN, CCK, MNR, DQA, FLL, DSK, DRG
Dated: April 14, 2014
Received: April 23, 2014

Dear Dr. Leigh Cornock,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

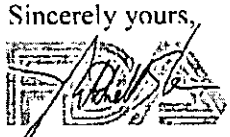
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

K133988
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510(k) Number (if known):

Device Name: Tempus Pro (EF)

Indications for Use:

The Tempus Pro is a portable vital signs monitor intended to be used by clinicians and medically qualified personnel for the attended or unattended monitoring of single or multiple vital signs in clinical and pre-hospital care applications. The device is indicated for 3 & 5 Lead ECG monitoring and 12 Lead ECG recording with interpretation, impedance pneumography, non-invasive blood pressure (NIBP), end-tidal CO2 (ETCO2), respiration rate, pulse oximetry (SpO2), contact temperature, invasive pressure and extended pulse oximetry capability including; carboxy haemoglobin (SpCO), metheglobin (SpMet), total haemoglobin (SpHb) and total oxygen content (SpOC) measurements.

The monitor is intended to be used as a stand-alone monitor or as a telemedicine system (transmitting patient data to other medical professionals located elsewhere).

The device is indicated for adults, pediatrics and neonates.

Prescription Use _V_____	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA Date: 2014.06.16 12:28:44 -04'00'